

5000 PCT #5

DT05 Rec'd PCT/PTO 13 DEC 2002



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: GELLERSFORS=2

In re Application of:)	Art Unit:
)	
Par GELLERSFORS)	Examiner:
)	
Appln. No.: 10/048,234)	Confirmation No.: 4358
)	
Filed: January 28, 2002)	Washington D.C.
)	
For: PRODUCTION OF pHPGD AND)	December 13, 2002
NEW THERAPEUTIC METHODS...)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

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☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c).

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. _____).

☐ D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

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[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[] A. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] B. Certain documents were previously cited by or

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submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[X] 3. Document BZ is not in the English language. In accordance with 1.98(c), Applicants state:

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- [] documents _____ already contain an English language abstract, summary or claim set.
- [X] a publicly available abstract is attached to document _____ BZ _____, and the source of each abstract is indicated thereon.
- [] documents _____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
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[insert]

[insert]

- [] applicants have prepared an English translation of at least the pertinent portions of documents _____, and copies are attached.
- [] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] A concise explanation of the relevance of documents _____ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's

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consideration follows:

[insert other information]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

7. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

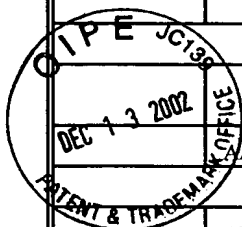
BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 

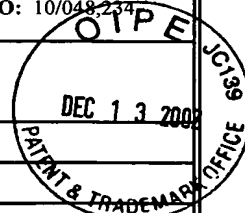
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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			ATTY DOCKET NO: GELLERFORS=2		SERIAL NO: 10/048,234			
LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)					APPLICANT: GELLERFORS, et al.					
					FILING DATE: January 28, 2002		GROUP:			
U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)										
EXAMINE R INITIAL		DOCUMENT NUMBER				DATE	PATENTEE	CLASS	SUB- CLASS	FILING DATE IF APPROP.
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)										
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)										
	AB	AMANN, et al., Vectors bearing a hybrid trp-lac promoter useful for regulated expression of cloned genes in <i>Escherichia coli</i> , GENE, vol. 25, pgs. 167-178, November 1983.								
	AC	ANDERSON, et al., Purification and Properties of Uroporphyrinogen I Synthase from Human Erythrocytes, THE JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 255, no. 5, pgs. 1993-1999, March 10, 1980.								
	AD	ANDERSSON, C., Thesis, Acute Intermittent Porphyria in Northern Sweden A Population-Based Study, ISBN 91/7191/280/0, 22-23, 1997.								
	AE	AWAN, et al., Reconstitution of the Holoenzyme Form of <i>Escherichia coli</i> Porphobilinogen Deaminase from Apoenzyme with Porphobilinogen and Preuroporphyrinogen: A Study Using Circular Dichroism Spectroscopy, BIOCHEMISTRY, vol. 36, no. 30, pgs. 9273-9282, May 1997.								
	AF	BEUTLER, et al., Enzyme Replacement Therapy for Gaucher Disease, BLOOD, Vol. 78, No. 5, pp. 1183-1189, September 1991.								
	AG	BRADY, et al., Evolution of Enzyme Replacement Therapy for Lipid Storage Diseases, LIFE SCIENCES, Vol. 15, pp. 1235-1248.								
	AH	BRADY, et al., Replacement Therapy for Inherited Enzyme Deficiency, THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 291, No. 19, pp. 989-993, November 1974.								
	AI	BROWNLIE, et al., The three-dimensional structures of mutants of porphobilinogen deaminase: Toward an understanding of the structural basis of acute intermittent porphyria, PROTEIN SCIENCE, Vol. 3, pp. 1644-1650, 1994								
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	AK	DARNELL, et al., Molecular Cell Biology, Third Edition, 299-300, Scientific American Books, 1995.								
	AL	DOSS, et al., Urinary Porphyrin Excretion Pattern and Isomer Distribution of I and III in Human Porphyrin Disorders, First International Porphyrin Meeting, Freiburg i.Br., pp. 189-204, 1975.								
	AM	DRANOFF, et al., Vaccination with irradiated tumor cells engineered to secrete murine granulocyte-macrophage colony-stimulating factor stimulates potent, specific, and long-lasting anti-tumor immunity, Proc. Natl. Acad. Sci., Vol. 90, pp. 3539-3543, April 1993.								
	AN	FEINSTEIN, et al., Reversal of H ₂ O ₂ toxicity in the acatalasemic mouse by catalase administration: Suggested model for possible replacement therapy of inborn errors of metabolism, J. LAB. & CLIN. MED., Vol. 68, No. 6, pp. 952-957, December 1996.								
	AO	FORMGREN, et al., Effects of Light of Different Wavelengths on the Porphyrin Concentration in the Harderian Gland of the Golden Hamster, Porphyrins in Human Diseases, 1 st Int. Porphyrin Meet. Freiburg/Br. pp. 380-384, Karger, Basel, 1976								
	AP	GOLD, et al., High-Level Translation Initiation, METHODS OF ENZYMOLOGY, vol. 185, pgs. 89-93, 1990.								
	AQ	GRAHAM, et al., Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5, J. Gen. Virol., Vol. 36, pp. 59-74, 1977.								
	AR	GRANDCHAMP, BERNARD, Acute Intermittent Porphyria, SEMINARS IN LIVER DISEASE, vol. 18, no. 1, pgs. 17-24, 1998.								
	AS	GRANDCHAMP, B., et al., Tissue-specific expression of porphobilinogen deaminase- Two isoenzymes from a single gene, Eur. J. Biochem. 162: 105-110, 1987.								
	AT	Abstract of GRANDCHAMP, B., et al., Review: molecular pathogenesis of hepatic acute porphyrias, J-Gastroenterol-Hepatol, 11(11): 1046-1052, 1996.								
	AU	GROB, et al., Haem Precursors and Porphobilinogen Deaminase in Erythrocytes and Lymphocytes of Patients with Acute Intermittent Porphyria, CELLULAR AND MOLECULAR BIOLOGY, vol. 43(1), pgs. 29-35, 1997.								
EXAMINER						DATE CONSIDERED				
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.										



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO: GELLERFORS=2	SERIAL NO: 10/048,234
LIST DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT: GELLERFORS, et al.	
		FILING DATE: January 28, 2002	GROUP:
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)			
AV	HERRICK, et al., <u>Controlled Trial of HAEM Arginate in Acute Hepatic Porphyria</u> , The Lancet, 1: 1295-1297, June 10, 1989.		
AW	JEANS, et al., <u>Mortality in Patients with Acute Intermittent Porphyria Requiring Hospitalization</u> , American Journal of Medical Genetics, 65: 269-273, 1996.		
AX	SHOOLINGIN-JORDAN, et al., <u>Dipyrromethane Cofactor Assembly of Porphobilinogen Deaminase: Formation of Apoenzyme and Preparation of Holoenzyme</u> , METHODS IN ENZYMOLOGY, vol. 281, pgs. 317-327, 1997.		
AY	JORDAN, et al., <u>Purification, crystallization and properties of porphobilinogen deaminase from a recombinant strain of Escherichia coli K12</u> , BIOCHEM. J., vol. 254, pgs. 427-435, 1988.		
AZ	JORDAN, Peter M., <u>The biosynthesis of uroporphyrinogen III: mechanism of action of porphobilinogen deaminase</u> , WILEY, CHICHESTER (CIBA FOUNDATION SYMPOSIUM 180), pgs. 70-96, 1994.		
BA	KAYA, et al., <u>Human δ-Aminolevulinic Dehydratase (ALAD) Gene: Structure and Alternative Splicing of the Erythroid and Housekeeping mRNAs</u> , GENOMICS, vol. 19, pgs. 242-248, 1994.		
BB	LAEMMLI, <u>Cleavage of Structural Proteins during the Assembly of the Head of Bacteriophage T4</u> , NATURE, vol. 227, pgs. 680-685, August 15, 1970.		
BC	LAMBERT, et al., <u>Structural studies on porphobilinogen deaminase</u> , WILEY, CHICHESTER (CIBA FOUNDATION SYMPOSIUM 180), pgs. 97-110, 1994.		
BD	LEE, et al., <u>Identification of the most common mutation within the porphobilinogen deaminase gene in Swedish patients with acute intermittent porphyria</u> , Proc. Natl. Acad. Sci., Vol. 88, pp. 10912-10915, December 1991.		
BE	LEWIS, et al., <u>Genetic and Molecular Analysis of Spontaneous Respiratory Deficient (res⁻) Mutants of Escherichia coli K-12</u> , MICROBIOL. IMMUNOL., vol. 35(4), pgs. 289-301, 1991.		
BF	LITHNER, et al., <u>Hepatocellular Carcinoma in Patients with Acute Intermittent Porphyria</u> , Acta. Med. Scand, 215: 271-274, 1984.		
BG	LOUIE, et al., <u>Structure of porphobilinogen deaminase reveals a flexible multidomain polymerase with a single catalytic site</u> , NATURE, Vol. 359, pp. 33-39, September 1992.		
BH	LOUIE, et al., <u>The Three-Dimensional Structure of Escherichia coli Porphobilinogen Deaminase at 1.76-Å Resolution</u> , PROTEINS: STRUCTURE, FUNCTION, AND GENETICS, vol. 25, pgs. 48-78, 1996.		
BI	MAKRIDES, Savvas C., <u>Strategies for Achieving High-Level Expression of Genes in Escherichia coli</u> , MICROBIOLOGICAL REVIEWS, vol. 60, no. 3, pgs. 512-538, September 1996.		
BJ	MANIATIS, et al., <u>Molecular Cloning A Laboratory Manual</u> , Cold Spring Harbor Laboratory, 440-44, 1982.		
BK	MANIATIS, et al., <u>Molecular Cloning A Laboratory Manual</u> , Cold Spring Harbor Laboratory, 150-160, 1982.		
BL	MEYER, et al., <u>Intermittant Acute Porphyria - Demonstration of a Genetic Defect in Porphobilinogen Metabolism</u> , The New England Journal of Medicine, Vol. 286, No. 24, pp. 1277-1282, June 15, 1972.		
BM	MILLER, et al., <u>Improved Retroviral Vectors for Gene Transfer and Expression</u> , BioTechniques, 7(9): 980-990, 1989.		
BN	MIYAGI, et al., <u>Uroporphyrinogen I synthase from human erythrocytes: Separation purification, and properties of isoenzymes</u> , PROC. NATL. ACAD. SCI. USA, vol. 76, no. 12, pgs. 6172-6176, December 1979.		
BO	MOREAU-GAUDRY, et al., <u>Correction of the Enzyme Defect in Cultured Congenital Erythropoietic Porphyria Disease Cells by Retrovirus-Mediated Gene Transfer</u> , Human Gene Therapy, Vol. 6, pp. 13-20, January 1995.		
BP	MORRISON, D.A., <u>Transformation and Preservation of Competent Bacterial Cells by Freezing</u> , METHODS IN ENZYMOLOGY, vol. 68, pgs. 326-331, 1979.		
BQ	MUSTAJOKI, et al., <u>Heme in the Treatment of Porphyrias and Hemotological Disorders</u> , Seminars in Hematology, January 1989, 26(1): 1-9		
BR	NOVEX, NuPAGE Electrophoresis System, Instruction Booklet, pgs. 1-27, 1997.		
BS	PIERCE INSTRUCTIONS, BCA Protein assay kit, Protein Assay, Technical Handbook, version 4/1997, pgs. 1-17, 1997.		
BT	RAICH, et al., <u>Molecular cloning and complete primary sequence of human erythrocyte porphobilinogen deaminase</u> , Nucleic Acid Research, 14(15): 5955-5968, 1986		
BU	SAIKI, et al., <u>Enzymatic Amplification of β-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia</u> , Science, 230: 1350-1354, December 1985.		
BV	SASSA, <u>Diagnosis and Therapy of Acute Intermittent Porphyria</u> , Blood Reviews, 10: 53-58, 1996.		
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PATENT AND TRADEMARK OFFICE**

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SERIAL NO: 10/048.234

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(Use several sheets if necessary)

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FILING DATE: January 28, 2002

GROUP:

DEC 13 2002

U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)

OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)

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